Available under BC PharmaCare when patients meet Special Authority criteria[1]

Prolia® is indicated:[2]

- For the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral and hip fractures.
- As a treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- As a treatment to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture.
- As a treatment to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, who have low bone mass and are at high risk for fracture.
- As a treatment to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy.
- As a treatment to increase bone mass in women and men at high risk for fracture who are starting or have recently started long-term glucocorticoid therapy.

Consult the Product Monograph at www.amgen.ca/Prolia_PM.pdf for important information relating to contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling us at 1-866-502-6436.

CRITERIA:[1]

For women with postmenopausal osteoporosis or men with osteoporosis with clinical or radiographically-documented fracture due to osteoporosis, and who are contraindicated to oral bisphosphonates for one of the following reasons:

- Immune-mediated hypersensitivity reaction to oral bisphosphonates; **OR**
- Abnormalities of the esophagus which delay esophageal emptying such as stricture or achalasia.

SPECIAL NOTES:

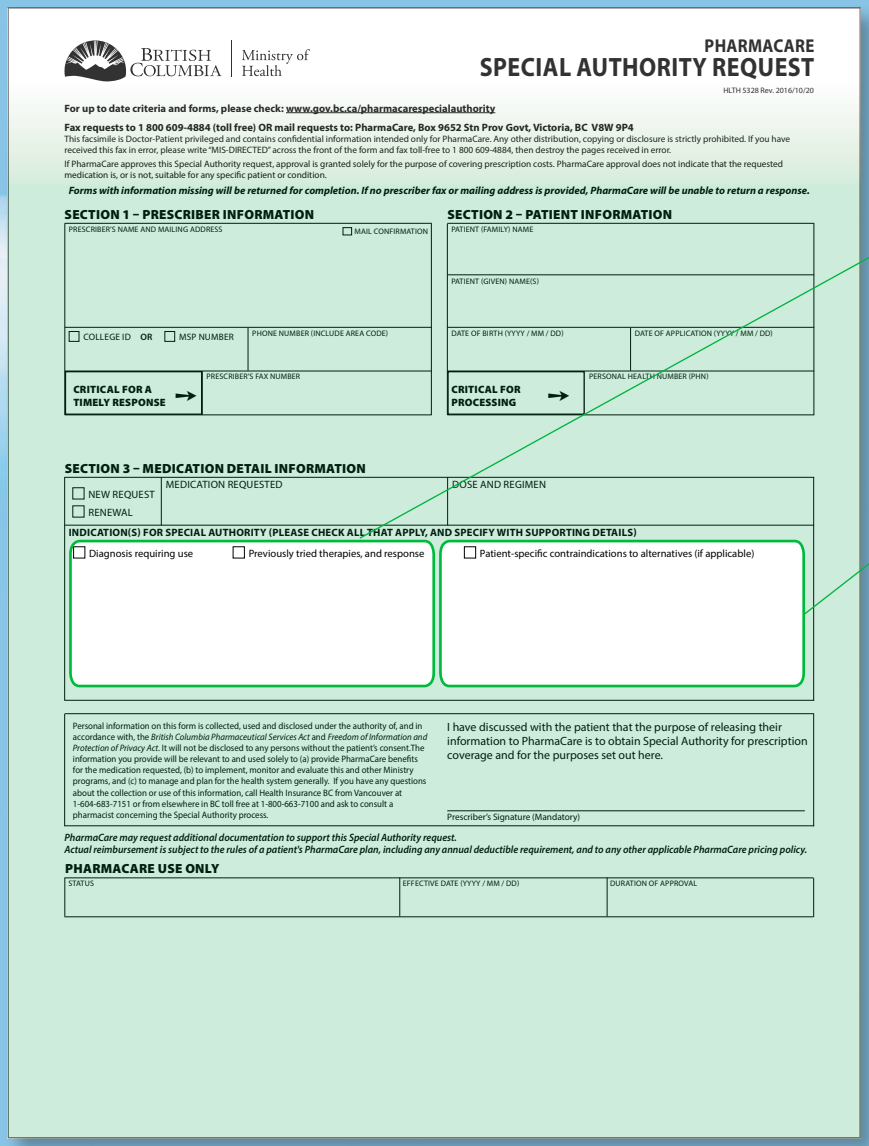
- Details regarding a patient's contraindication to oral bisphosphonates are required as part of the Special Authority request
- Clinical fracture is defined as a symptomatic (painful) fracture
- Radiographically-documented fracture is defined as a fracture identified by X-ray (e.g. vertebral compression fracture). This may be asymptomatic

Pr prolia® denosumab

REVIEWED BY PAAB

References: 1. British Columbia PharmaCare program. Limited Coverage Drugs – Denosumab. Accessed May 31, 2018. https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/prescribers/limited-coverage-drug-program/limited-coverage-drugs-denosumab. **2.** Prolia Product Monograph. Amgen Canada Inc., June 25, 2019.

British Columbia Form – "How To"



BRITISH COLUMBIA | Ministry of Health

PHARMACARE
SPECIAL AUTHORITY REQUEST

HLTH 5328 Rev. 2016/10/20

For up to date criteria and forms, please check: www.gov.bc.ca/pharmacarespecialauthority

Fax requests to 1 800 609-4884 (toll free) OR mail requests to: PharmaCare, Box 9652 Stn Prov Govt, Victoria, BC V8W 9P4

This facsimile is Doctor-Patient privileged and contains confidential information intended only for PharmaCare. Any other distribution, copying or disclosure is strictly prohibited. If you have received this fax in error, please write "MIS-DIRECTED" across the front of the form and fax toll-free to 1 800 609-4884, then destroy the pages received in error.

If PharmaCare approves this Special Authority request, approval is granted solely for the purpose of covering prescription costs. PharmaCare approval does not indicate that the requested medication is, or is not, suitable for any specific patient or condition.

Forms with information missing will be returned for completion. If no prescriber fax or mailing address is provided, PharmaCare will be unable to return a response.

SECTION 1 – PRESCRIBER INFORMATION

PRESCRIBER'S NAME AND MAILING ADDRESS — ☐ MAIL CONFIRMATION

☐ COLLEGE ID **OR** ☐ MSP NUMBER | PHONE NUMBER (INCLUDE AREA CODE)

CRITICAL FOR A TIMELY RESPONSE → | PRESCRIBER'S FAX NUMBER

SECTION 2 – PATIENT INFORMATION

PATIENT (FAMILY) NAME

PATIENT (GIVEN) NAME(S)

DATE OF BIRTH (YYYY / MM / DD) | DATE OF APPLICATION (YYYY / MM / DD)

CRITICAL FOR PROCESSING → | PERSONAL HEALTH NUMBER (PHN)

SECTION 3 – MEDICATION DETAIL INFORMATION

☐ NEW REQUEST
☐ RENEWAL

MEDICATION REQUESTED | DOSE AND REGIMEN

INDICATION(S) FOR SPECIAL AUTHORITY (PLEASE CHECK ALL THAT APPLY, AND SPECIFY WITH SUPPORTING DETAILS)

☐ Diagnosis requiring use ☐ Previously tried therapies, and response

☐ Patient-specific contraindications to alternatives (if applicable)

Personal information on this form is collected, used and disclosed under the authority of, and in accordance with, the *British Columbia Pharmaceutical Services Act* and *Freedom of Information and Protection of Privacy Act*. It will not be disclosed to any persons without the patient's consent.The information you provide will be relevant to and used solely to (a) provide PharmaCare benefits for the medication requested, (b) to implement, monitor and evaluate this and other Ministry programs, and (c) to manage and plan for the health system generally. If you have any questions about the collection or use of this information, call Health Insurance BC from Vancouver at 1-604-683-7151 or from elsewhere in BC toll free at 1-800-663-7100 and ask to consult a pharmacist concerning the Special Authority process.

I have discussed with the patient that the purpose of releasing their information to PharmaCare is to obtain Special Authority for prescription coverage and for the purposes set out here.

Prescriber's Signature (Mandatory)

PharmaCare may request additional documentation to support this Special Authority request.
Actual reimbursement is subject to the rules of a patient's PharmaCare plan, including any annual deductible requirement, and to any other applicable PharmaCare pricing policy.

PHARMACARE USE ONLY

STATUS | EFFECTIVE DATE (YYYY / MM / DD) | DURATION OF APPROVAL

For use in women with postmenopausal osteoporosis or men with osteoporosis with clinical or radiographically-documented fracture due to osteoporosis

Form **MUST** indicate that bisphosphonate use is contraindicated due to hypersensitivity or patient has abnormalities of the esophagus

Pr prolia® denosumab

REVIEWED BY PAAB

Available under the Alberta Health & Wellness Drug Benefit List via Special Authorization[1]

Prolia® is indicated:[2]

- For the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral and hip fractures.
- As a treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- As a treatment to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture.
- As a treatment to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, who have low bone mass and are at high risk for fracture.
- As a treatment to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy.
- As a treatment to increase bone mass in women and men at high risk for fracture who are starting or have recently started long-term glucocorticoid therapy.

Consult the Product Monograph at www.amgen.ca/Prolia_PM.pdf for important information relating to contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling us at 1-866-502-6436.

CRITERIA:[1]

For the treatment of osteoporosis in patients who have a high 10-year risk (i.e. greater than 20%) of experiencing a major osteoporotic fracture OR a moderate 10-year fracture risk (10-20%) and have experienced a prior fragility fracture.

AND at least one of the following:

1) For whom oral bisphosphonates are contraindicated due to drug-induced hypersensitivity (i.e. immunologically mediated); **OR**

2) For whom oral bisphosphonates are contraindicated due to an abnormality of the esophagus which delays esophageal emptying; **OR**

3) For whom bisphosphonates are contraindicated due to severe renal impairment (i.e. creatinine clearance <35 mL/min); **OR**

4) Who have demonstrated severe gastrointestinal intolerance to a course of therapy with either alendronate or risedronate; **OR**

5) Who had an unsatisfactory response (defined as a fragility fracture despite adhering to oral alendronate or risedronate treatment fully for 1 year and evidence of a decline in BMD below pretreatment baseline level).

Note: Fracture risk can be determined by the World Health Organization's Fracture Risk Assessment Tool (FRAX) or the most recent (2010) version of the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) table.

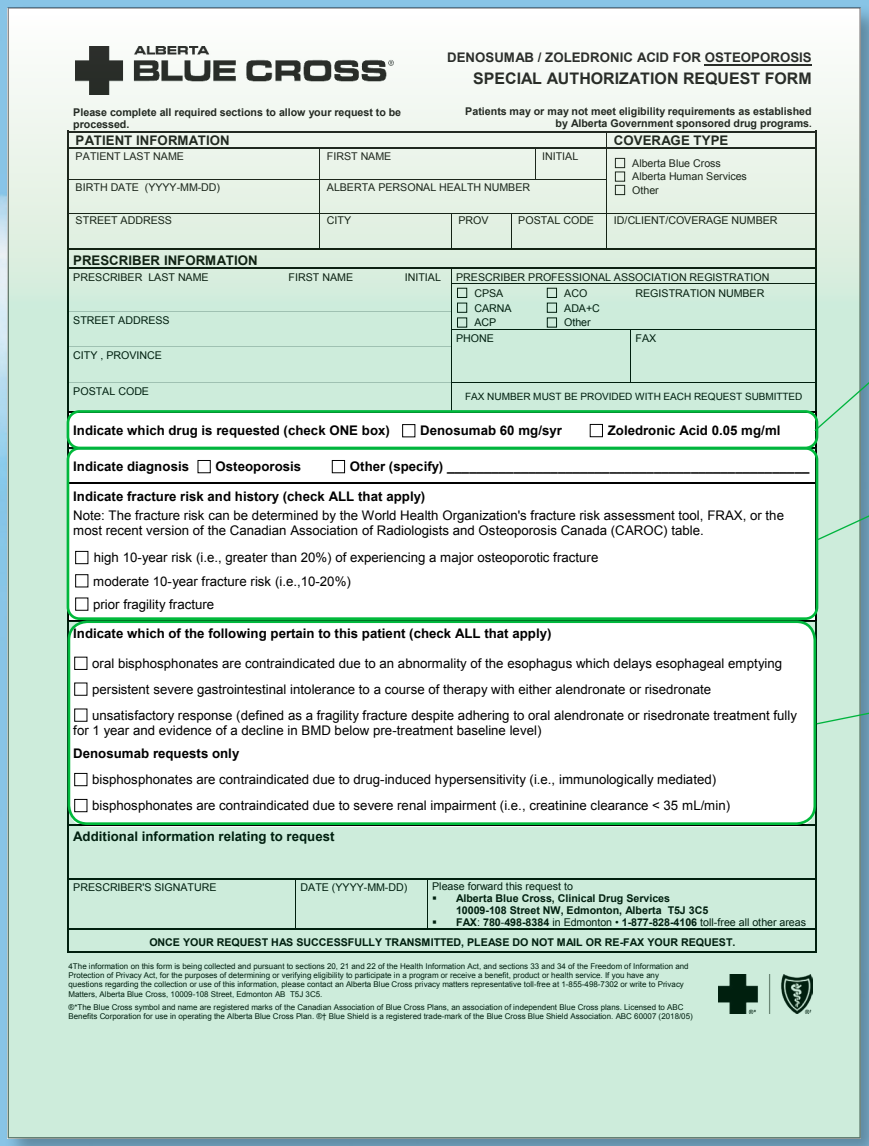
Special authorization may be granted for 12 months. Patients will be limited to receiving one dose of denosumab per prescription at their pharmacy. Coverage cannot be provided for two or more osteoporosis medications (alendronate, denosumab, raloxifene, risedronate, zoledronic acid) when these medications are intended for use as combination therapy. Requests for other osteoporosis medications covered via special authorization will not be considered until 6 months after the last dose of denosumab 60 mg/syr injection syringe. Requests for other osteoporosis medications covered via special authorization will not be considered until 12 months after the last dose of zoledronic acid 0.05 mg/mL injection. All requests for denosumab must be completed using the Denosumab/Zoledronic Acid for Osteoporosis Special Authorization Request Form (ABC 60007).

Pr prolia® denosumab

REVIEWED BY PAAB

References: 1. Government of Alberta Health and Wellness. Updates to the Alberta Health and Wellness Drug Benefit List, June 1, 2018. Accessed June 1, 2018. https://www.ab.bluecross.ca/dbl/pdfs/jun_dblupdate.pdf. **2.** Prolia Product Monograph. Amgen Canada Inc., June 25, 2019.

Alberta Blue Cross Form – "How To"



ALBERTA BLUE CROSS®

DENOSUMAB / ZOLEDRONIC ACID FOR OSTEOPOROSIS
SPECIAL AUTHORIZATION REQUEST FORM

Please complete all required sections to allow your request to be processed.

Patients may or may not meet eligibility requirements as established by Alberta Government sponsored drug programs.

PATIENT INFORMATION

PATIENT LAST NAME	FIRST NAME	INITIAL	COVERAGE TYPE
			☐ Alberta Blue Cross ☐ Alberta Human Services ☐ Other
BIRTH DATE (YYYY-MM-DD)	ALBERTA PERSONAL HEALTH NUMBER		
STREET ADDRESS	CITY / PROV / POSTAL CODE		ID/CLIENT/COVERAGE NUMBER

PRESCRIBER INFORMATION

PRESCRIBER LAST NAME / FIRST NAME / INITIAL	PRESCRIBER PROFESSIONAL ASSOCIATION REGISTRATION
	☐ CPSA ☐ ACO ☐ CARNA ☐ ADA+C ☐ ACP ☐ Other — REGISTRATION NUMBER
STREET ADDRESS	PHONE / FAX
CITY , PROVINCE	
POSTAL CODE	FAX NUMBER MUST BE PROVIDED WITH EACH REQUEST SUBMITTED

Indicate which drug is requested (check ONE box) ☐ **Denosumab 60 mg/syr** ☐ **Zoledronic Acid 0.05 mg/ml**

Indicate diagnosis ☐ **Osteoporosis** ☐ **Other (specify)** _____

Indicate fracture risk and history (check ALL that apply)

Note: The fracture risk can be determined by the World Health Organization's fracture risk assessment tool, FRAX, or the most recent version of the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) table.

☐ high 10-year risk (i.e., greater than 20%) of experiencing a major osteoporotic fracture
☐ moderate 10-year fracture risk (i.e.,10-20%)
☐ prior fragility fracture

Indicate which of the following pertain to this patient (check ALL that apply)

☐ oral bisphosphonates are contraindicated due to an abnormality of the esophagus which delays esophageal emptying
☐ persistent severe gastrointestinal intolerance to a course of therapy with either alendronate or risedronate
☐ unsatisfactory response (defined as a fragility fracture despite adhering to oral alendronate or risedronate treatment fully for 1 year and evidence of a decline in BMD below pre-treatment baseline level)

Denosumab requests only

☐ bisphosphonates are contraindicated due to drug-induced hypersensitivity (i.e., immunologically mediated)
☐ bisphosphonates are contraindicated due to severe renal impairment (i.e., creatinine clearance < 35 mL/min)

Additional information relating to request

PRESCRIBER'S SIGNATURE	DATE (YYYY-MM-DD)	Please forward this request to
		• **Alberta Blue Cross, Clinical Drug Services** **10009-108 Street NW, Edmonton, Alberta T5J 3C5** • **FAX**: **780-498-8384** in Edmonton • **1-877-828-4106** toll-free all other areas

ONCE YOUR REQUEST HAS SUCCESSFULLY TRANSMITTED, PLEASE DO NOT MAIL OR RE-FAX YOUR REQUEST.

4The information on this form is being collected and pursuant to sections 20, 21 and 22 of the Health Information Act, and sections 33 and 34 of the Freedom of Information and Protection of Privacy Act, for the purposes of determining or verifying eligibility to participate in a program or receive a benefit, product or health service. If you have any questions regarding the collection or use of this information, please contact an Alberta Blue Cross privacy matters representative toll-free at 1-855-498-7302 or write to Privacy Matters, Alberta Blue Cross, 10009-108 Street, Edmonton AB T5J 3C5.

®†The Blue Cross symbol and name are registered marks of the Canadian Association of Blue Cross Plans, an association of independent Blue Cross plans. Licensed to ABC Benefits Corporation for use in operating the Alberta Blue Cross Plan. ®† Blue Shield is a registered trade-mark of the Blue Cross Blue Shield Association. ABC 60007 (2018/05)

Indicate the requested drug

Form **MUST** indicate diagnosis and fracture risk/history for male and female patients

AND at least **ONE** of the following:

Pr prolia® denosumab

REVIEWED BY PAAB

Available for men and postmenopausal women with osteoporosis under the Saskatchewan Drug Plan's Exception Drug Status (EDS) Program[1]

Prolia® is indicated:[2]

- For the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral and hip fractures.
- As a treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- As a treatment to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture.
- As a treatment to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, who have low bone mass and are at high risk for fracture.
- As a treatment to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy.
- As a treatment to increase bone mass in women and men at high risk for fracture who are starting or have recently started long-term glucocorticoid therapy.

Consult the Product Monograph at www.amgen.ca/Prolia_PM.pdf for important information relating to contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling us at 1-866-502-6436.

CRITERIA:[1]

For men and postmenopausal women with osteoporosis

To increase bone mass in men or postmenopausal women with osteoporosis who are at a high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy, where the following clinical criteria are met:[1]

- High fracture risk*, **AND**
- Contraindication to oral bisphosphonates.†

* High fracture risk is defined as either:
- Moderate 10-year fracture risk (10% to 20%) with a prior fragility fracture;

OR
- High 10-year fracture risk (≥20%).

Fracture risks above as defined by either the CAROC tool or the World Health Organization's FRAX tool.

† Notes:
- Bisphosphonate failure will be defined as a fragility fracture and/or evidence of a decline in bone mineral density below pretreatment baseline levels, despite adherence for one year.
- Contraindication to oral bisphosphonates will be considered. Contraindications include renal impairment, hypersensitivity and abnormalities of the esophagus (e.g. esophageal stricture or achalasia).

For men on ADT for prostate cancer and women on AI for breast cancer

For the treatment of osteoporosis in patients with moderate-high 10-year fracture risk (10% or more) and one of the following:[1]

- Men on androgen deprivation therapy for prostate cancer; **OR**
- Women on aromatase inhibitor therapy for breast cancer.

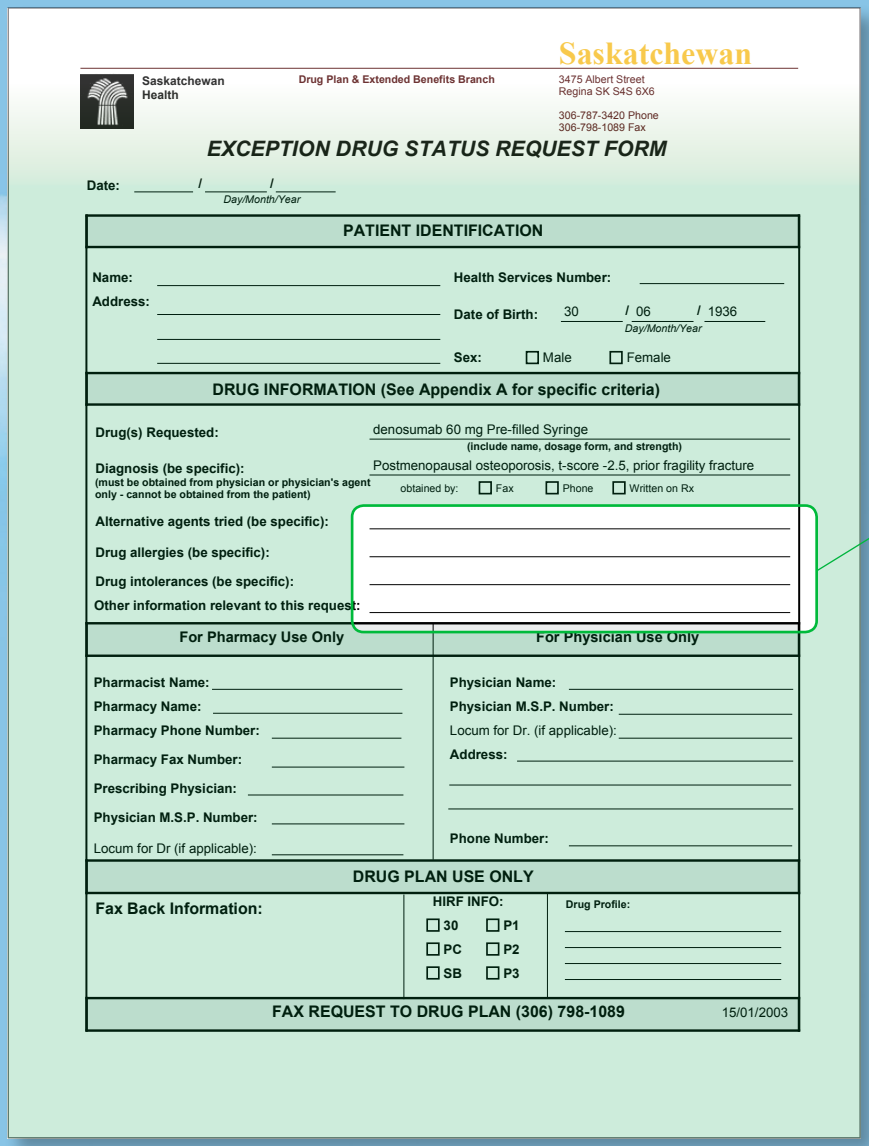
ADT=androgen deprivation therapy; AI=aromatase inhibitor; CAROC=Canadian Association of Radiologists and Osteoporosis Canada; EDS=exception drug status; FRAX=Fracture Risk Assessment

Pr prolia® denosumab

REVIEWED BY PAAB

References: 1. Saskatchewan Formulary Bulletin #168, January 1, 2018. Accessed February 7, 2018. http://formulary.drugplan.ehealthsask.ca/Bulletins/Bulletin168Jan2018.pdf. **2.** Prolia Product Monograph. Amgen Canada Inc., June 25, 2019.

Saskatchewan Form – "How To"



Saskatchewan

Saskatchewan Health

Drug Plan & Extended Benefits Branch

3475 Albert Street
Regina SK S4S 6X6

306-787-3420 Phone
306-798-1089 Fax

EXCEPTION DRUG STATUS REQUEST FORM

Date: _____ / _____ / _____
Day/Month/Year

PATIENT IDENTIFICATION

Name: _____ Health Services Number: _____

Address: _____ Date of Birth: 30 / 06 / 1936
Day/Month/Year

_____ Sex: ☐ Male ☐ Female

DRUG INFORMATION (See Appendix A for specific criteria)

Drug(s) Requested: denosumab 60 mg Pre-filled Syringe
(include name, dosage form, and strength)

Diagnosis (be specific): Postmenopausal osteoporosis, t-score -2.5, prior fragility fracture
(must be obtained from physician or physician's agent only - cannot be obtained from the patient) obtained by: ☐ Fax ☐ Phone ☐ Written on Rx

Alternative agents tried (be specific): _____

Drug allergies (be specific): _____

Drug intolerances (be specific): _____

Other information relevant to this request: _____

For Pharmacy Use Only	For Physician Use Only
Pharmacist Name:	Physician Name:
Pharmacy Name:	Physician M.S.P. Number:
Pharmacy Phone Number:	Locum for Dr. (if applicable):
Pharmacy Fax Number:	Address:
Prescribing Physician:	
Physician M.S.P. Number:	
Locum for Dr (if applicable):	Phone Number:

DRUG PLAN USE ONLY

Fax Back Information:

HIRF INFO:
☐ 30 ☐ P1
☐ PC ☐ P2
☐ SB ☐ P3

Drug Profile:

FAX REQUEST TO DRUG PLAN (306) 798-1089 15/01/2003

Form **MUST** indicate that patient with osteoporosis is:

- At high risk of fracture or failed or is intolerant to other available osteoporosis therapies, where the following clinical criteria are met: high risk of fracture, **AND** contraindication to bisphosphonates (including renal impairment, hypersensitivity and abnormalities of the esophagus).
- On ADT for prostate cancer (men) or AI for breast cancer (women) and has moderate-high 10-year fracture risk.

Pr prolia® denosumab

REVIEWED BY PAAB

Available under the Manitoba Drug Benefits and Interchangeability Formulary's Exception Drug Status Program[1]

Prolia® is indicated:[2]

- For the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral and hip fractures.
- As a treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- As a treatment to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture.
- As a treatment to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, who have low bone mass and are at high risk for fracture.
- As a treatment to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy.
- As a treatment to increase bone mass in women and men at high risk for fracture who are starting or have recently started long-term glucocorticoid therapy.

Consult the Product Monograph at www.amgen.ca/Prolia_PM.pdf for important information relating to contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling us at 1-866-502-6436.

CRITERIA:[1]

To increase bone mass in men or postmenopausal women with osteoporosis at a high risk for fracture OR who have failed OR are intolerant to other available osteoporosis therapy, where the following clinical criteria are met:

- High fracture risk defined as either:
  - Moderate 10-year fracture risk (10-20%) as defined by either the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool with a prior fragility fracture

OR

  - High 10-year fracture risk (≥20%) as defined by either the CAROC or FRAX tool

AND

- Contraindication to oral bisphosphonates

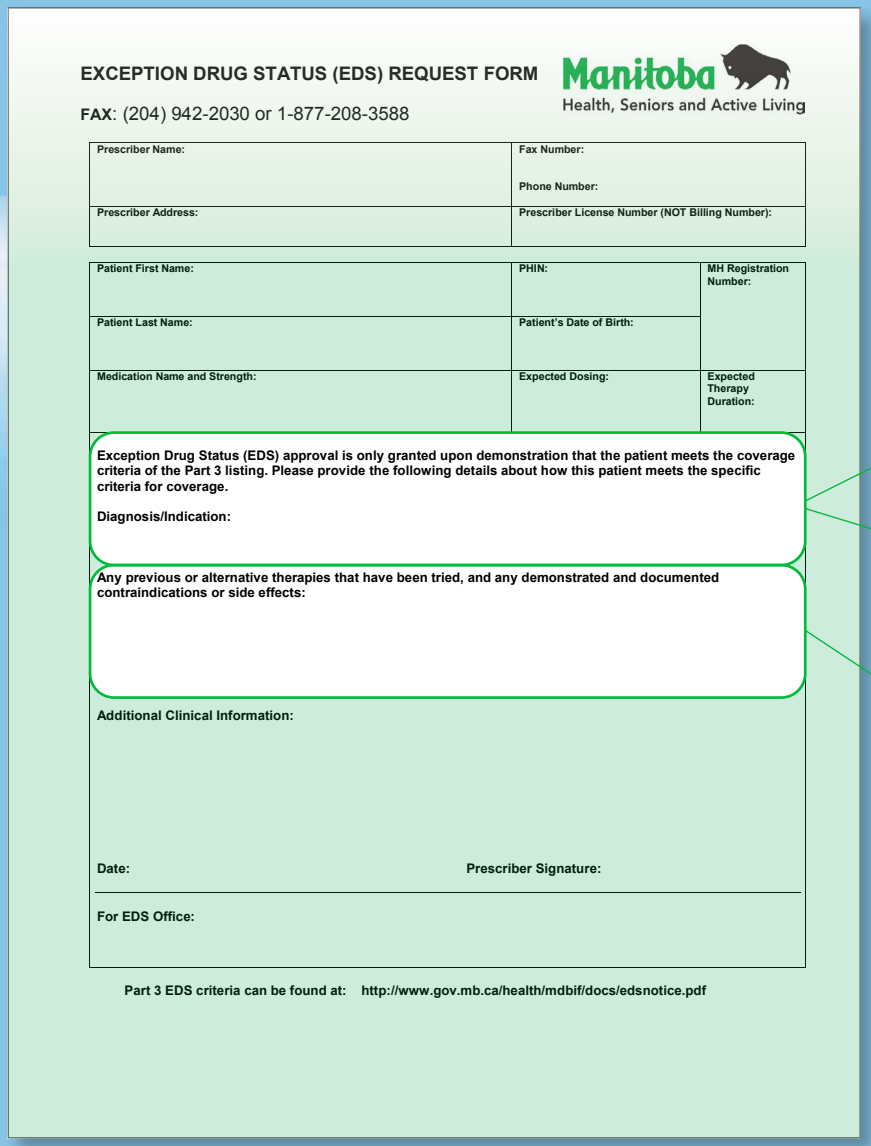
Notes: Bisphosphonate failure will be defined as a fragility fracture and/or evidence of a decline in bone mineral density below pretreatment baseline levels, despite adherence for one year. Contraindication to oral bisphosphonates will be considered, including: renal impairment, hypersensitivity and abnormalities of the esophagus (e.g. esophageal stricture or achalasia).

Pr prolia® denosumab

REVIEWED BY PAAB

References: 1. Government of Manitoba. Exception Drug Status (EDS) Formulary Update. Accessed May 31, 2018. https://www.gov.mb.ca/health/mdbif/docs/edsnotice.pdf. **2.** Prolia Product Monograph. Amgen Canada Inc., June 25, 2019.

Manitoba Form – "How To"



EXCEPTION DRUG STATUS (EDS) REQUEST FORM

Manitoba
Health, Seniors and Active Living

FAX: (204) 942-2030 or 1-877-208-3588

Prescriber Name:	**Fax Number:** **Phone Number:**
Prescriber Address:	**Prescriber License Number (NOT Billing Number):**

Patient First Name:	**PHIN:**	**MH Registration Number:**
Patient Last Name:	**Patient's Date of Birth:**	
Medication Name and Strength:	**Expected Dosing:**	**Expected Therapy Duration:**

Exception Drug Status (EDS) approval is only granted upon demonstration that the patient meets the coverage criteria of the Part 3 listing. Please provide the following details about how this patient meets the specific criteria for coverage.

Diagnosis/Indication:

Any previous or alternative therapies that have been tried, and any demonstrated and documented contraindications or side effects:

Additional Clinical Information:

Date: **Prescriber Signature:**

For EDS Office:

Part 3 EDS criteria can be found at: http://www.gov.mb.ca/health/mdbif/docs/edsnotice.pdf

For use in men or postmenopausal women with osteoporosis at high risk of fracture **OR** who have failed **OR** are intolerant to other available osteoporosis therapy

Form **MUST** include clinical criteria indicating high fracture risk

AND previous therapies tried and any contraindications and/or side effects to bisphosphonates

Requests can be submitted by telephone, mail or fax. A toll-free line with an electronic message system is available exclusively for requests on a 24-hour basis. The telephone number to access this line is (204) 788-6388 or 1-800-557-4303.

Pr prolia® denosumab

REVIEWED BY PAAB

Available for both men and postmenopausal women with osteoporosis by the Ontario formulary and most private drug plans[1]

Prolia® is indicated:[2]

- For the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral and hip fractures.
- As a treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- As a treatment to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture.
- As a treatment to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, who have low bone mass and are at high risk for fracture.
- As a treatment to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy.
- As a treatment to increase bone mass in women and men at high risk for fracture who are starting or have recently started long-term glucocorticoid therapy.

Consult the Product Monograph at www.amgen.ca/Prolia_PM.pdf for important information relating to contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling us at 1-866-502-6436.

CRITERIA:[1]

To increase bone mass in males and postmenopausal females with osteoporosis who meet the following criteria:[1]

High risk for fracture; and

Failed other available osteoporosis therapy (i.e. fragility fracture **OR** evidence of a decline in bone mineral density below pretreatment baseline levels) despite adherence for one year.	For whom oral bisphosphonates are contraindicated due to hypersensitivity **OR** abnormalities of the esophagus (e.g. esophageal stricture or achalasia) **OR** inability to stand or sit upright for at least 30 minutes.
♀ LU Code 428 ♂ LU Code 515	♀ LU Code 429 ♂ LU Code 516

High fracture risk is defined as:[1]
- A prior fragility fracture AND a moderate 10-year fracture risk (10% to 20%); OR
- A high 10-year fracture risk (≥20%); OR
- Where a patient's 10-year fracture risk is less than the thresholds defined above, a high fracture risk based on evaluation of clinical risk factors for fracture.

All above definitions are based on the CAROC or FRAX tool.

Notes:
- Use of the CAROC or FRAX tool may underestimate fracture risk in certain circumstances and may not include all risk factors.
- In all cases, patients on Prolia must not be receiving concomitant bisphosphonate therapy. Recommended dose of Prolia is a single SC injection of 60 mg, once every 6 months.

LU Authorization Period: Indefinite

CAROC=Canadian Association of Radiologists and Osteoporosis Canada; FRAX=Fracture Risk Assessment

Pr prolia® denosumab

REVIEWED BY PAAB

References: 1. Ontario Drug Benefit Formulary/Comparative Drug Index Edition 43. Accessed February 7, 2018. http://www.health.gov.on.ca/en/pro/programs/drugs/formulary43/summary_edition43_20180124.pdf. **2.** Prolia Product Monograph. Amgen Canada Inc., June 25, 2019.

Available for both postmenopausal women (code MS153) and men with osteoporosis under *Régie de l'assurance maladie du Québec* (RAMQ) via Special Authorization[1]

Prolia® is indicated:[2]

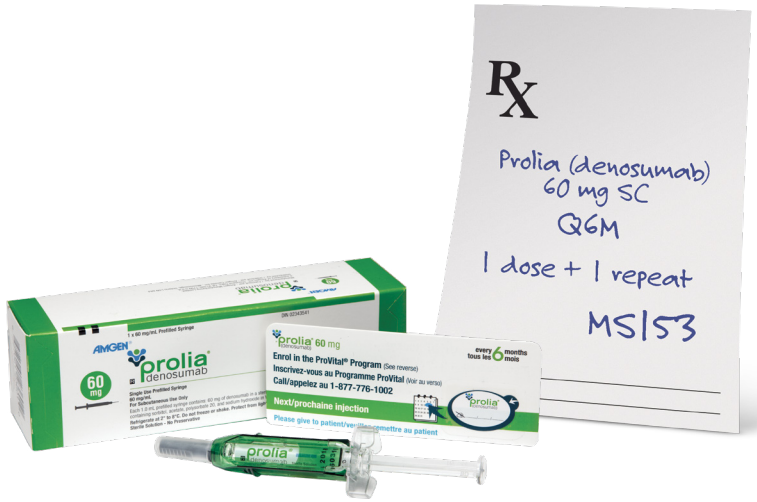
- For the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral and hip fractures.
- As a treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- As a treatment to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture.
- As a treatment to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, who have low bone mass and are at high risk for fracture.
- As a treatment to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy.
- As a treatment to increase bone mass in women and men at high risk for fracture who are starting or have recently started long-term glucocorticoid therapy.

Consult the Product Monograph at www.amgen.ca/Prolia_PM.pdf for important information relating to contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling us at 1-866-502-6436.

CRITERIA:[1]

- **For the treatment of postmenopausal osteoporosis (PMO) in women who cannot take an oral bisphosphonate due to serious intolerance or contraindication.**
- **For the treatment of osteoporosis in men at high risk of fracture who cannot take an oral bisphosphonate due to serious intolerance or contraindication.**

"RAMQ" is the official mark of the *Régie de l'assurance maladie du Québec*.



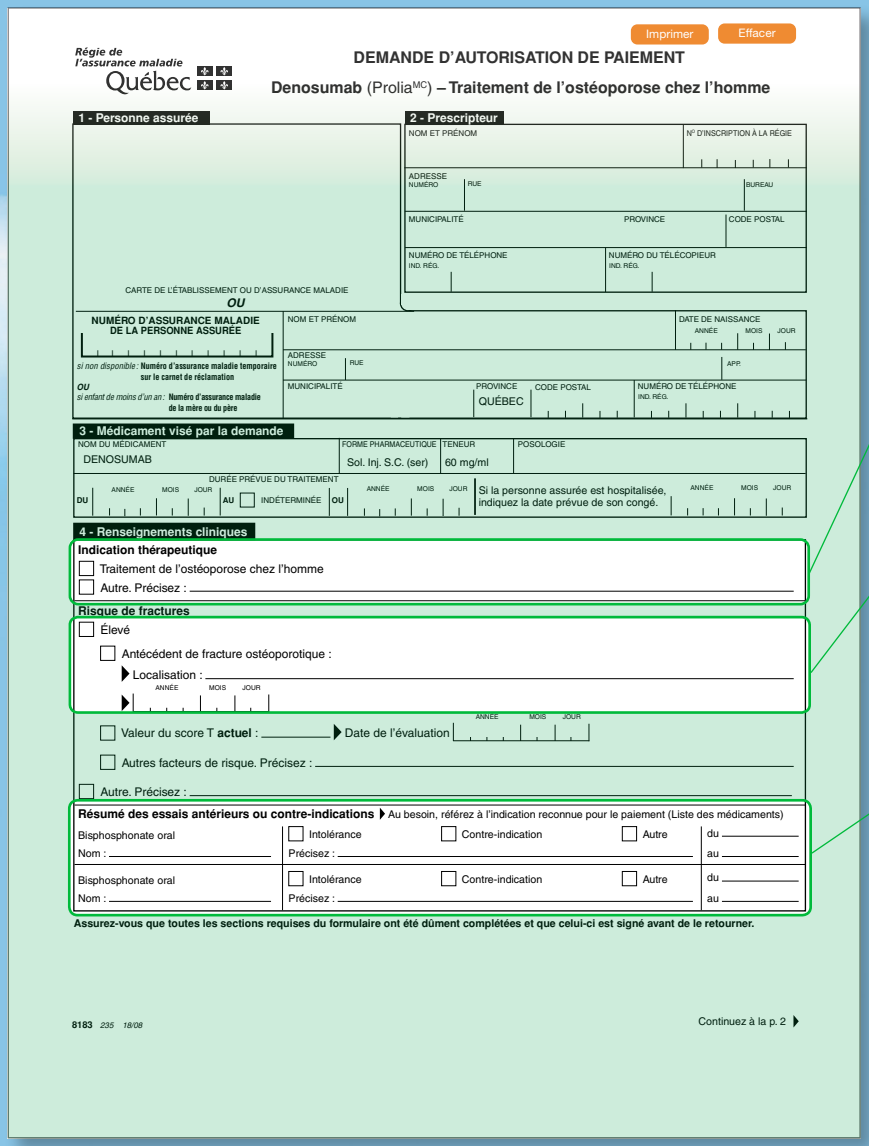
Prolia is also covered by all private drug plans in Quebec.

prolia® denosumab

REVIEWED BY PAAB

References: 1. Régie de l'assurance maladie Québec. Liste de médicaments – Établissements – Modification nº1 et Correction nº1, 32e édition, entrant en vigueur le 16 août 2018. Accessed August 17, 2018. http://www.ramq.gouv.qc.ca/fr/professionnels/medicaments/demande_medicament_exception_mc.shtml. **2.** Prolia Product Monograph. Amgen Canada Inc., June 25, 2019.

RAMQ Form – "How To"



Imprimer Effacer

Régie de l'assurance maladie Québec

DEMANDE D'AUTORISATION DE PAIEMENT

Denosumab (Prolia[MC]) – Traitement de l'ostéoporose chez l'homme

1 - Personne assurée

CARTE DE L'ÉTABLISSEMENT OU D'ASSURANCE MALADIE

OU

NUMÉRO D'ASSURANCE MALADIE DE LA PERSONNE ASSURÉE

si non disponible : **Numéro d'assurance maladie temporaire sur le carnet de réclamation**

OU

si enfant de moins d'un an : **Numéro d'assurance maladie de la mère ou du père**

2 - Prescripteur

NOM ET PRÉNOM | N° D'INSCRIPTION À LA RÉGIE

ADRESSE NUMÉRO | RUE | BUREAU

MUNICIPALITÉ | PROVINCE | CODE POSTAL

NUMÉRO DE TÉLÉPHONE IND. RÉG. | NUMÉRO DU TÉLÉCOPIEUR IND. RÉG.

NOM ET PRÉNOM | DATE DE NAISSANCE ANNÉE MOIS JOUR

ADRESSE NUMÉRO | RUE | APP.

MUNICIPALITÉ | PROVINCE QUÉBEC | CODE POSTAL | NUMÉRO DE TÉLÉPHONE IND. RÉG.

3 - Médicament visé par la demande

NOM DU MÉDICAMENT	FORME PHARMACEUTIQUE	TENEUR	POSOLOGIE
DENOSUMAB	Sol. Inj. S.C. (ser)	60 mg/ml	

DURÉE PRÉVUE DU TRAITEMENT

DU ANNÉE MOIS JOUR AU ☐ INDÉTERMINÉE OU ANNÉE MOIS JOUR

Si la personne assurée est hospitalisée, indiquez la date prévue de son congé. ANNÉE MOIS JOUR

4 - Renseignements cliniques

Indication thérapeutique

☐ Traitement de l'ostéoporose chez l'homme

☐ Autre. Précisez : _____

Risque de fractures

☐ Élevé

☐ Antécédent de fracture ostéoporotique :

▶ Localisation : _____

▶ ANNÉE MOIS JOUR

☐ Valeur du score T **actuel** : _____ ▶ Date de l'évaluation ANNÉE MOIS JOUR

☐ Autres facteurs de risque. Précisez : _____

☐ Autre. Précisez : _____

Résumé des essais antérieurs ou contre-indications ▶ Au besoin, référez à l'indication reconnue pour le paiement (Liste des médicaments)

Bisphosphonate oral Nom : _____	☐ Intolérance	☐ Contre-indication	☐ Autre Précisez : _____	du _____ au _____
Bisphosphonate oral Nom : _____	☐ Intolérance	☐ Contre-indication	☐ Autre Précisez : _____	du _____ au _____

Assurez-vous que toutes les sections requises du formulaire ont été dûment complétées et que celui-ci est signé avant de le retourner.

8183 235 18/08

Continuez à la p. 2 ▶

MALE OSTEOPOROSIS

Specify the indication for use.

Form **MUST** indicate that the patient is at a high risk of fracture. Indicate where and when the prior fracture(s) occurred, the T-score with date and any additional risk factors.

Form **MUST** indicate that bisphosphonates cannot be used due to serious intolerance or contraindication.

Pr prolia® denosumab

REVIEWED BY PAAB

Available under the Nova Scotia Health & Wellness Public Drug Plan – Exception Status Benefit[1]

Prolia® is indicated:[2]

- For the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral and hip fractures.
- As a treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- As a treatment to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture.
- As a treatment to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, who have low bone mass and are at high risk for fracture.
- As a treatment to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy.
- As a treatment to increase bone mass in women and men at high risk for fracture who are starting or have recently started long-term glucocorticoid therapy.

Consult the Product Monograph at www.amgen.ca/Prolia_PM.pdf for important information relating to contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling us at 1-866-502-6436.

CRITERIA:[1]

For the treatment of osteoporosis in postmenopausal women and male patients who meet the following criteria:

- Have a contraindication to oral bisphosphonates; and
- High risk for fracture, or refractory or intolerant to other available osteoporosis therapies.

CLINICAL NOTES:

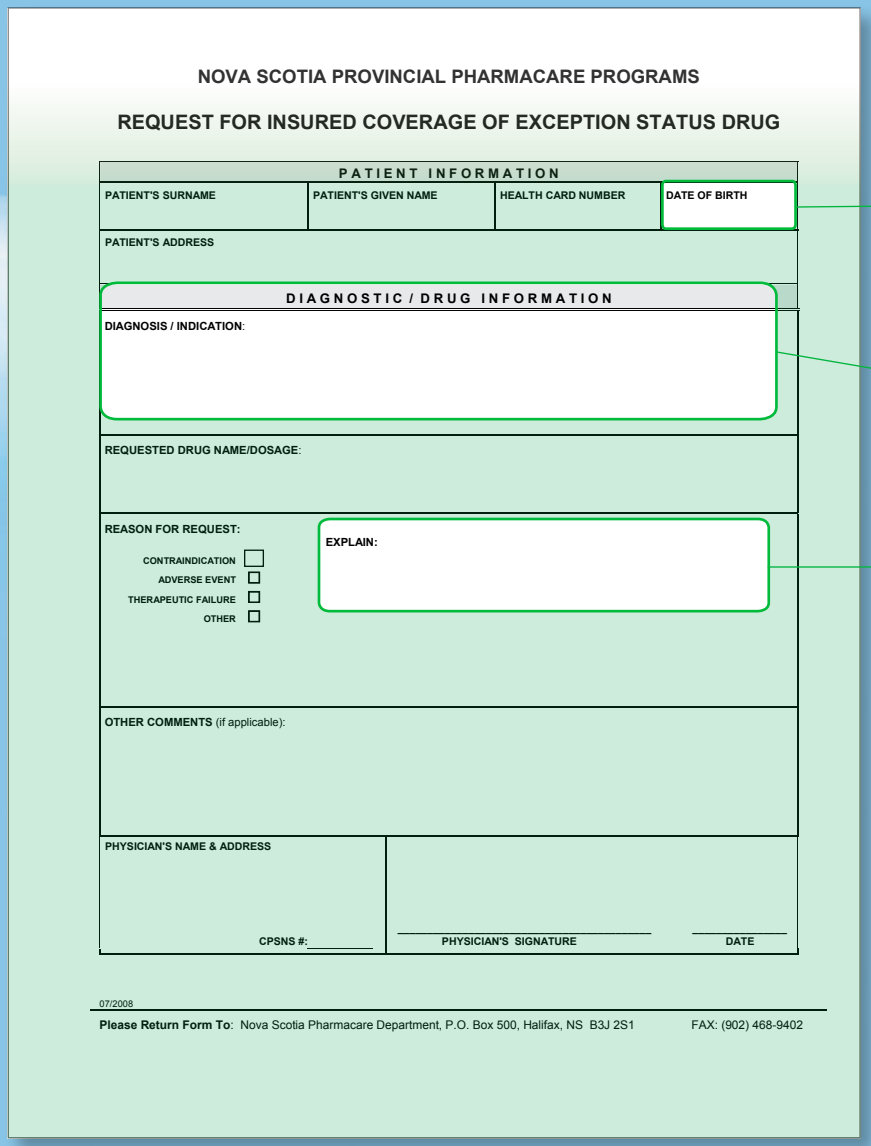
- Refractory is defined as a fragility fracture or evidence of a decline in bone mineral density below pretreatment baseline levels, despite adherence for one year to other available osteoporosis therapies.
- High fracture risk defined as:
  - Moderate 10-year fracture risk (10% to 20%) as defined by the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool with a prior fragility fracture; or
  - High 10-year fracture risk (≥20%) as defined by CAROC or FRAX tool.

Pr prolia® denosumab

REVIEWED BY PAAB

References: 1. Government of Nova Scotia Health and Wellness. Nova Scotia Formulary. Accessed August 8, 2019. https://novascotia.ca/dhw/pharmacare/documents/formulary.pdf. **2.** Prolia Product Monograph. Amgen Canada Inc., June 25, 2019.

Nova Scotia Form – "How To"



NOVA SCOTIA PROVINCIAL PHARMACARE PROGRAMS

REQUEST FOR INSURED COVERAGE OF EXCEPTION STATUS DRUG

PATIENT INFORMATION

PATIENT'S SURNAME	PATIENT'S GIVEN NAME	HEALTH CARD NUMBER	DATE OF BIRTH

PATIENT'S ADDRESS

DIAGNOSTIC / DRUG INFORMATION

DIAGNOSIS / INDICATION:

REQUESTED DRUG NAME/DOSAGE:

REASON FOR REQUEST:

- CONTRAINDICATION ☐
- ADVERSE EVENT ☐
- THERAPEUTIC FAILURE ☐
- OTHER ☐

EXPLAIN:

OTHER COMMENTS (if applicable):

PHYSICIAN'S NAME & ADDRESS

CPSNS #:_____

PHYSICIAN'S SIGNATURE _____ DATE _____

07/2008

Please Return Form To: Nova Scotia Pharmacare Department, P.O. Box 500, Halifax, NS B3J 2S1 FAX: (902) 468-9402

For use in men or postmenopausal women with osteoporosis at high risk of fracture **OR** who have failed **OR** are intolerant to other available osteoporosis therapy

Form **MUST** include clinical criteria indicating high fracture risk

AND previous therapies tried and any contraindications and/or side effects to bisphosphonates

Pr prolia® denosumab

REVIEWED BY PAAB

Available under the Newfoundland and Labrador Public Drug Program via Special Authorization[1]

Prolia® is indicated:[2]

- For the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral and hip fractures.
- As a treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- As a treatment to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture.
- As a treatment to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, who have low bone mass and are at high risk for fracture.
- As a treatment to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy.
- As a treatment to increase bone mass in women and men at high risk for fracture who are starting or have recently started long-term glucocorticoid therapy.

Consult the Product Monograph at www.amgen.ca/Prolia_PM.pdf for important information relating to contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling us at 1-866-502-6436.

CRITERIA:[1]

For the treatment of osteoporosis in postmenopausal women and male patients who meet the following criteria:

- Have a contraindication to oral bisphosphonates

AND

- High risk for fracture, or refractory or intolerant to other available osteoporosis therapies

Clinical criteria:

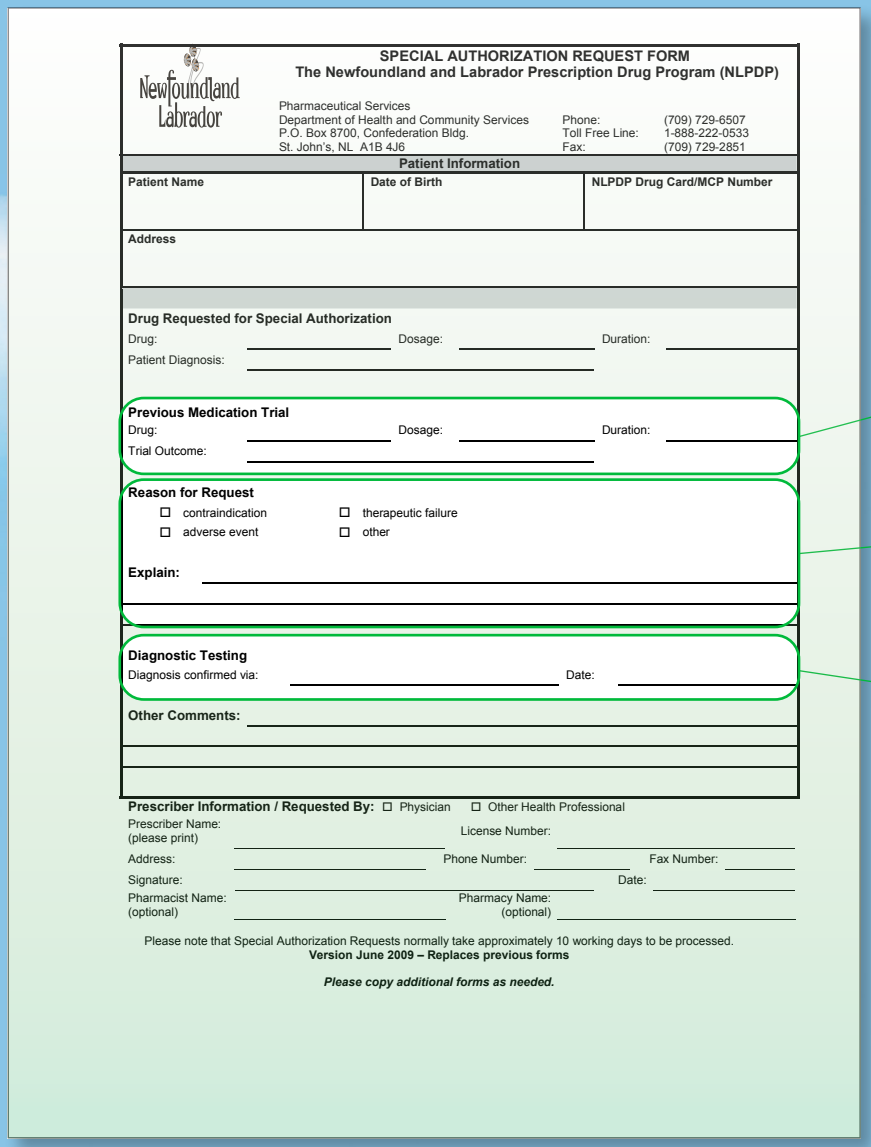
- High fracture risk defined as either: a moderate 10-year fracture risk (10-20%) with a prior fragility fracture OR a high 10-year fracture risk (≥20%) as defined by either the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool
- Refractory is defined as an unsatisfactory response to bisphosphonates and is typically defined as a fragility fracture and/or evidence of a decline in bone mineral density below pretreatment baseline levels, despite adherence for one year

Pr prolia® denosumab

REVIEWED BY PAAB

References: 1. Government of Newfoundland and Labrador. Department of Health and Community Services. Special Authorization Drug Products. Updated March 2018. Accessed May 31, 2018. http://www.health.gov.nl.ca/health/prescription/newformulary.asp. **2.** Prolia Product Monograph. Amgen Canada Inc., June 25, 2019.

Newfoundland and Labrador Form – "How To"



Newfoundland Labrador

SPECIAL AUTHORIZATION REQUEST FORM
The Newfoundland and Labrador Prescription Drug Program (NLPDP)

Pharmaceutical Services
Department of Health and Community Services
P.O. Box 8700, Confederation Bldg.
St. John's, NL A1B 4J6

Phone: (709) 729-6507
Toll Free Line: 1-888-222-0533
Fax: (709) 729-2851

Patient Information

Patient Name	Date of Birth	NLPDP Drug Card/MCP Number

Address

Drug Requested for Special Authorization

Drug: _____ Dosage: _____ Duration: _____

Patient Diagnosis: _____

Previous Medication Trial

Drug: _____ Dosage: _____ Duration: _____

Trial Outcome: _____

Reason for Request

☐ contraindication ☐ therapeutic failure
☐ adverse event ☐ other

Explain: _____

Diagnostic Testing

Diagnosis confirmed via: _____ Date: _____

Other Comments: _____

Prescriber Information / Requested By: ☐ Physician ☐ Other Health Professional

Prescriber Name: (please print) _____ License Number: _____

Address: _____ Phone Number: _____ Fax Number: _____

Signature: _____ Date: _____

Pharmacist Name: (optional) _____ Pharmacy Name: (optional) _____

Please note that Special Authorization Requests normally take approximately 10 working days to be processed.
Version June 2009 – Replaces previous forms

Please copy additional forms as needed.

Indicate previous treatment(s) and outcome

Form **MUST** indicate contraindication to bisphosphonate use **AND** high fracture risk OR patient is intolerant OR refractory to available therapies

Form **MUST** indicate the clinical criteria indicating high fracture risk

Pr prolia® denosumab

REVIEWED BY PAAB

Available for both men and postmenopausal women with osteoporosis under the New Brunswick Prescription Drug Program via Special Authorization[1]

Prolia® is indicated:[2]

- For the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral and hip fractures.
- As a treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- As a treatment to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture.
- As a treatment to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, who have low bone mass and are at high risk for fracture.
- As a treatment to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy.
- As a treatment to increase bone mass in women and men at high risk for fracture who are starting or have recently started long-term glucocorticoid therapy.

Consult the Product Monograph at www.amgen.ca/Prolia_PM.pdf for important information relating to contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling us at 1-866-502-6436.

CRITERIA:[1]

For the treatment of osteoporosis in postmenopausal women and in men who meet the following criteria:[1]

- Have a contraindication to oral bisphosphonates;

AND

- High risk for fracture*, or refractory or intolerant to other available osteoporosis therapies.

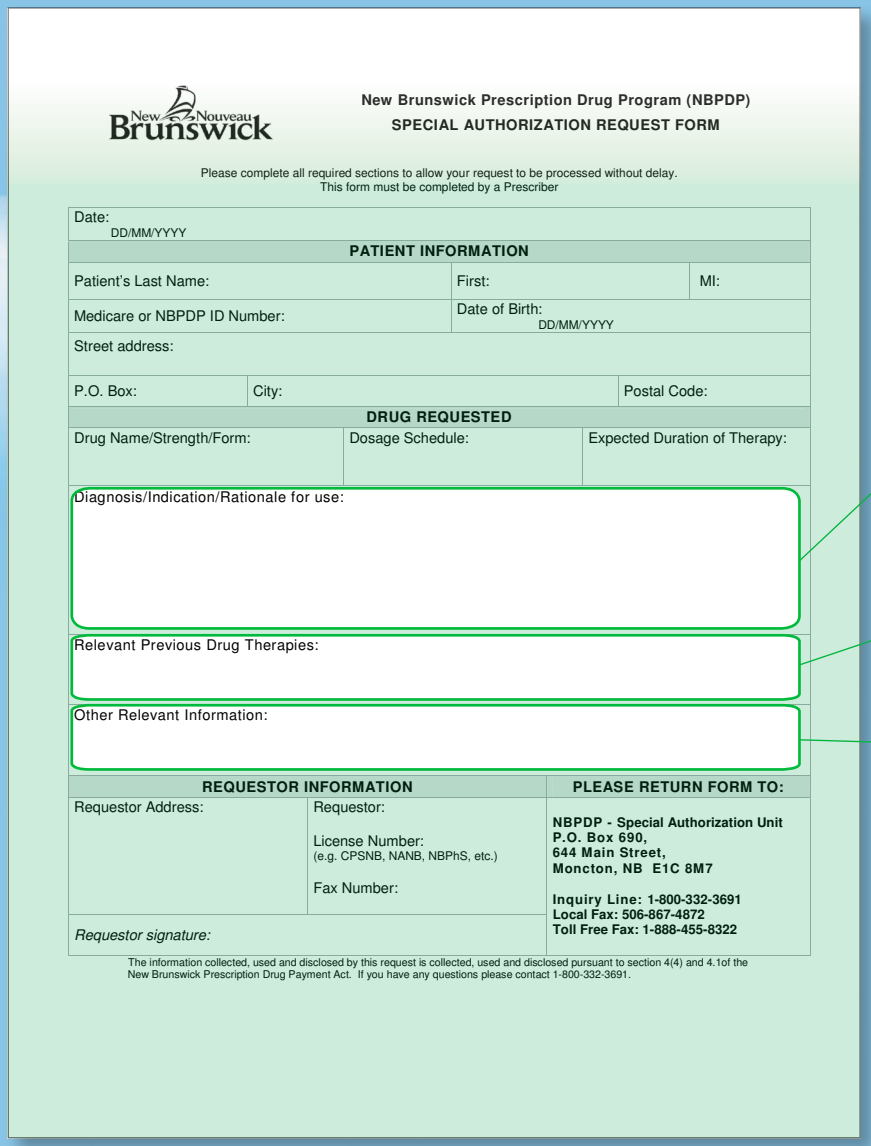
* High fracture risk is defined as:
- A moderate 10-year fracture risk (10% to 20%) as defined by the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool with a prior fragility fracture; or
- A high 10-year fracture risk (≥20%) as defined by either the CAROC or FRAX tool.

Pr prolia® denosumab

REVIEWED BY PAAB

References: 1. New Brunswick Drug Plans Formulary Bulletin #965, January 22, 2018. Accessed February 7, 2018. http://www2.gnb.ca/content/dam/gnb/Departments/h-s/pdf/en/NBDrugPlan/FormularyUpdates/NBDrugPlansBulletin965.pdf. **2.** Prolia Product Monograph. Amgen Canada Inc., June 25, 2019.

New Brunswick Form – "How To"



New Brunswick Nouveau-Brunswick

New Brunswick Prescription Drug Program (NBPDP)
SPECIAL AUTHORIZATION REQUEST FORM

Please complete all required sections to allow your request to be processed without delay.
This form must be completed by a Prescriber

Date: DD/MM/YYYY

PATIENT INFORMATION

Patient's Last Name:	First:	MI:
Medicare or NBPDP ID Number:	Date of Birth: DD/MM/YYYY	
Street address:		
P.O. Box:	City:	Postal Code:

DRUG REQUESTED

Drug Name/Strength/Form:	Dosage Schedule:	Expected Duration of Therapy:

Diagnosis/Indication/Rationale for use:

Relevant Previous Drug Therapies:

Other Relevant Information:

REQUESTOR INFORMATION		PLEASE RETURN FORM TO:
Requestor Address:	Requestor: License Number: (e.g. CPSNB, NANB, NBPhS, etc.) Fax Number:	**NBPDP - Special Authorization Unit** **P.O. Box 690,** **644 Main Street,** **Moncton, NB E1C 8M7** **Inquiry Line: 1-800-332-3691** **Local Fax: 506-867-4872** **Toll Free Fax: 1-888-455-8322**
Requestor signature:		

The information collected, used and disclosed by this request is collected, used and disclosed pursuant to section 4(4) and 4.1of the New Brunswick Prescription Drug Payment Act. If you have any questions please contact 1-800-332-3691.

For use in male patients with osteoporosis or female patients with postmenopausal osteoporosis in whom bisphosphonate use is contraindicated and where the patient is at high risk of fracture, or refractory or intolerant to other available osteoporosis therapies.

Form **MUST** indicate previous therapies that the patient was refractory to or could not tolerate.

Form **MUST** indicate that bisphosphonate use is contraindicated.

Pr prolia® denosumab

REVIEWED BY PAAB

Available under PEI Pharmacare when patients meet Special Authority criteria[1]

Prolia® is indicated:[2]

- For the treatment of postmenopausal women with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Prolia reduces the incidence of vertebral, nonvertebral and hip fractures.
- As a treatment to increase bone mass in men with osteoporosis at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.
- As a treatment to increase bone mass in men with nonmetastatic prostate cancer receiving androgen deprivation therapy (ADT), who are at high risk for fracture.
- As a treatment to increase bone mass in women with nonmetastatic breast cancer receiving adjuvant aromatase inhibitor (AI) therapy, who have low bone mass and are at high risk for fracture.
- As a treatment to increase bone mass in women and men at high risk for fracture due to sustained systemic glucocorticoid therapy.
- As a treatment to increase bone mass in women and men at high risk for fracture who are starting or have recently started long-term glucocorticoid therapy.

Consult the Product Monograph at www.amgen.ca/Prolia_PM.pdf for important information relating to contraindications, warnings, precautions, adverse reactions, interactions, dosing and conditions of clinical use. The Product Monograph is also available by calling us at 1-866-502-6436.

CRITERIA:[1]

For the treatment of osteoporosis in postmenopausal women who were previously approved or would otherwise be eligible for coverage of oral bisphosphonates and who:

1. Have experienced a further significant decline in bone mineral density (BMD) after 1 year of continuous bisphosphonate therapy and meet at least **TWO** of the following:
   - Age >75 years old
   - Prior fragility fracture
   - BMD T-score ≤-2.5

OR

2. Have a contraindication to bisphosphonates due to hypersensitivity or abnormalities of the esophagus (e.g. esophageal stricture or achalasia) and have at least **TWO** of the following:
   - Age >75 years old
   - Prior fragility fracture
   - BMD T-score ≤-2.5

NOTE: Hypersensitivity or abnormalities are defined as esophageal ulceration, erosion or stricture, or lower gastrointestinal symptoms severe enough to cause discontinuation of oral bisphosphonates, or swallowing disorders that will increase the risk of esophageal ulceration from oral bisphosphonates.

In all cases, patients receiving Prolia (denosumab) must not be receiving concomitant bisphosphonate therapy.

The recommended dose of Prolia (denosumab) is a single subcutaneous injection of 60 mg, once every 6 months.

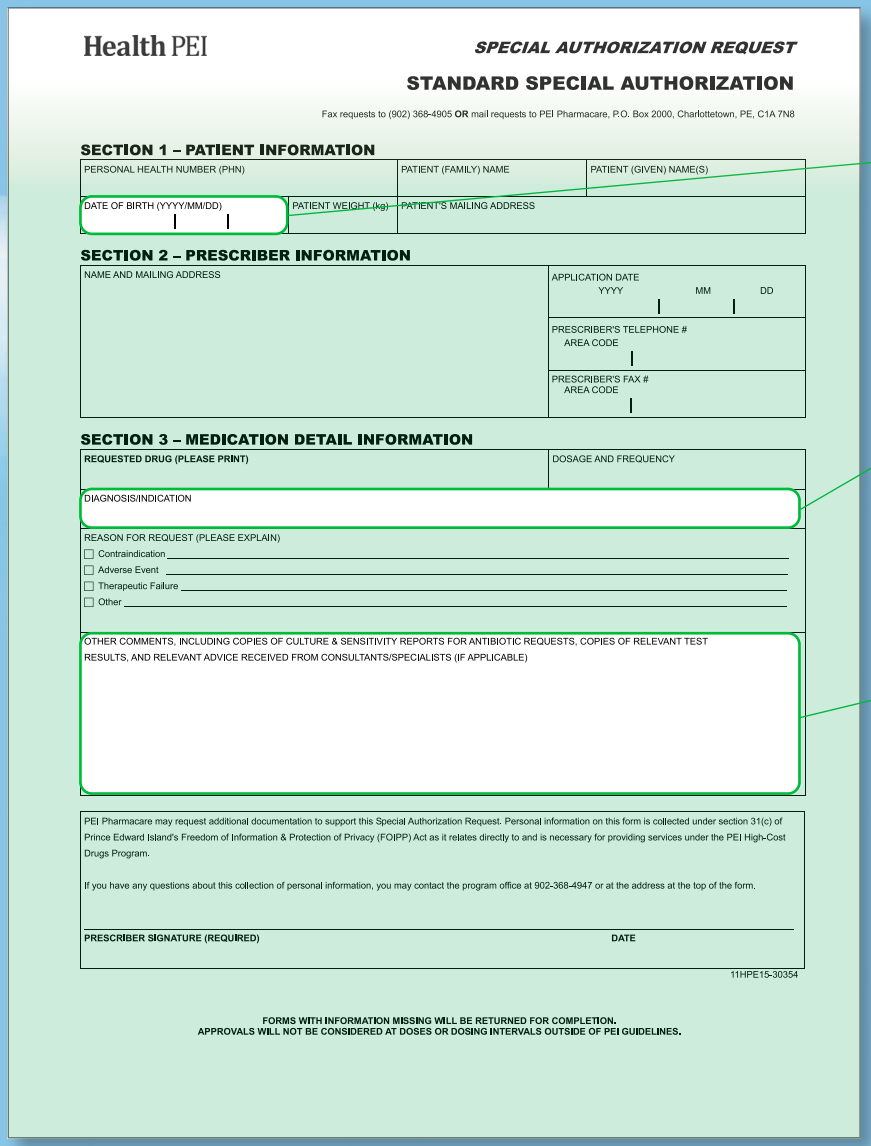
For full details regarding coverage, visit www.healthpei.ca/formulary.

Pr prolia® denosumab

REVIEWED BY PAAB

References: 1. Health PEI: P.E.I. Pharmacare Formulary. Accessed March 13, 2014. http://www.gov.pe.ca/photos/original/hpei_formulary.pdf.
2. Prolia Product Monograph. Amgen Canada Inc., June 25, 2019.

PEI Form – "How To"



Health PEI

SPECIAL AUTHORIZATION REQUEST

STANDARD SPECIAL AUTHORIZATION

Fax requests to (902) 368-4905 **OR** mail requests to PEI Pharmacare, P.O. Box 2000, Charlottetown, PE, C1A 7N8

SECTION 1 – PATIENT INFORMATION

PERSONAL HEALTH NUMBER (PHN)	PATIENT (FAMILY) NAME	PATIENT (GIVEN) NAME(S)
DATE OF BIRTH (YYYY/MM/DD)	PATIENT WEIGHT (kg)	PATIENT'S MAILING ADDRESS

SECTION 2 – PRESCRIBER INFORMATION

NAME AND MAILING ADDRESS	APPLICATION DATE YYYY MM DD
	PRESCRIBER'S TELEPHONE # AREA CODE
	PRESCRIBER'S FAX # AREA CODE

SECTION 3 – MEDICATION DETAIL INFORMATION

REQUESTED DRUG (PLEASE PRINT)	DOSAGE AND FREQUENCY

DIAGNOSIS/INDICATION

REASON FOR REQUEST (PLEASE EXPLAIN)

- ☐ Contraindication
- ☐ Adverse Event
- ☐ Therapeutic Failure
- ☐ Other

OTHER COMMENTS, INCLUDING COPIES OF CULTURE & SENSITIVITY REPORTS FOR ANTIBIOTIC REQUESTS, COPIES OF RELEVANT TEST RESULTS, AND RELEVANT ADVICE RECEIVED FROM CONSULTANTS/SPECIALISTS (IF APPLICABLE)

PEI Pharmacare may request additional documentation to support this Special Authorization Request. Personal information on this form is collected under section 31(c) of Prince Edward Island's Freedom of Information & Protection of Privacy (FOIPP) Act as it relates directly to and is necessary for providing services under the PEI High-Cost Drugs Program.

If you have any questions about this collection of personal information, you may contact the program office at 902-368-4947 or at the address at the top of the form.

PRESCRIBER SIGNATURE (REQUIRED) **DATE**

11HPE15-30354

FORMS WITH INFORMATION MISSING WILL BE RETURNED FOR COMPLETION.
APPROVALS WILL NOT BE CONSIDERED AT DOSES OR DOSING INTERVALS OUTSIDE OF PEI GUIDELINES.

Age: If older than 75 years, the patient meets one of the 3 additional criteria.

If older than 75 years of age, the patient must indicate that **EITHER** the T-score is ≤-2.5 or they have had a prior fragility fracture.

Otherwise patients **MUST** meet **BOTH** of these additional criteria.

Form **MUST** indicate that the patient has experienced a significant decline in bone mineral density (BMD), in which case bisphosphonate use is contraindicated due to hypersensitivity or patient having abnormalities of the esophagus.

Pr prolia® denosumab

REVIEWED BY PAAB